**Formulary Changes**

**Sildenafil – 1st Line Oral Choice for Erectile Dysfunction**

Due to the impending loss of patent for sildenafil (Viagra®) in June 2013, the ADTC have approved the use of sildenafil as the 1st line oral treatment option for patients with erectile dysfunction. Sildenafil should be preferred in all new patients requiring treatment before considering alternative options such as tadalafil (Cialis®) or vardenafil (Levitra®).

Patients currently prescribed tadalafil or vardenafil can remain on their current treatment unless a switch to sildenafil is considered appropriate. The urology department have confirmed that their erectile dysfunction clinic, where appropriate, will now also recommend the use of sildenafil as their 1st line choice.

**Key Message**
Sildenafil is the preferred oral treatment for new patients diagnosed with erectile dysfunction.

**Fultium D3® - 1st Licensed Vitamin D Product**

Fultium-D3® is the first oral vitamin D monotherapy product to be licensed in the UK. The ADTC, have approved the use of Fultium D3® for the following indications:

- **Vitamin D Deficiency** - 1st line choice for all causes of vitamin D deficiency.
- **Primary Hyperparathyroidism** - 1st line choice for vitamin D insufficiency in symptomatic patients with primary hyperparathyroidism.
- **Osteoporosis** - Restricted use when calcium + vit. D products are considered unsuitable, ineffective due to non-compliance or are not tolerated.

Fultium-D3® is contraindicated in patients allergic to peanuts or soya and is not licensed for use in children below 12 years of age.

**Guidance Document**

Fife Formulary Appendix 9C - Advice on Prescribing of VitaminD3® Products has been developed to advise prescribers when to test and monitor vitamin D levels, indications for prescribing Fultium D3® and also doses and duration of treatment for different indications.

Appendix 9C has been distributed electronically within NHS Fife. Further copies can be accessed / downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Fife Formulary or via the Fife Formulary link on the NHS Fife intranet homepage.

**Flutiform® - New Combination MDI for Asthma**

Flutiform® (fluticasone propionate and formoterol fumarate) metered dose inhaler has been approved by the ADTC as a 2nd line treatment option at Step 3 for asthma in patients, aged 12 years and above.

The 1st choice combination inhaler remains Fostair® (beclometasone 100mcg/ formoterol 6mcg), with 2nd line choices being flutiform®, Seretide® (fluticasone/salmeterol) and Symbicort® (budesonide/formoterol).

Flutiform® is cheaper than equivalent doses of Seretide® or Symbicort® and should be considered in new patients when Fostair® is not appropriate.

**Key Messages**

1. Fostair® remains the 1st choice combination inhaler for use in asthma patients.
2. Flutiform® should be considered in new patients when Fostair® is unsuitable.
**Ticagrelor (Brilique®) – Approved for Restricted Use**

Ticagrelor (Brilique®), a new oral antiplatelet agent, has been approved for restricted use by the ADTC in high risk patients with a non-ST elevated myocardial infarction (NSTEMI) for the prevention of an atherothrombotic event.

Ticagrelor, 90mg twice daily, is co-administered with aspirin for a period of 12 months after which the ticagrelor should be discontinued. Patients should then continue long-term aspirin.

Ticagrelor should only be initiated by a cardiologist in patients who are considered to be high risk.

Due to the significant cost of ticagrelor, the combination of clopidogrel and aspirin will continue to be used in the majority of patients with acute coronary syndrome.

**Key Messages**

1. Clopidogrel + aspirin remains the combination of choice in most patients with acute coronary syndrome.
2. Ticagrelor should only be initiated by cardiologists for use in patients with a NSTEMI who are considered at high risk of an atherothrombotic event.
3. A stop date should entered onto prescribing systems to ensure patients are reviewed and the ticagrelor discontinued 12 months after patients have been initiated on ticagrelor.

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**Duloxetine – Approved for Restricted Use in Fibromyalgia**

The ADTC have approved the use of duloxetine as a 3rd line treatment option for patients with fibromyalgia. THE ADTC have not approved the use of duloxetine for neuropathic pain.

Duloxetine should be initiated by or on the advice of a pain specialist for 3rd line use in patients where 1st line agents (tricyclics) and 2nd line agent (gabapentin) are considered unsuitable, have been ineffective or are not tolerated. As duloxetine is an antidepressant, duloxetine may be of benefit in patients with concomitant low mood.

Like other agents, duloxetine is not licensed for use in fibromyalgia and this would be an ‘off-label’ use.

The ADTC has previously approved the use of duloxetine as a 3rd line option in patients with peripheral diabetic neuropathy.

Duloxetine is more expensive than other treatment options e.g. tricyclics, gabapentin but would be cheaper than pregabalin (3rd line alternative).

**Key Message**

Duloxetine may be prescribed as a 3rd line option in patients with fibromyalgia when initiated/recommended by a pain specialist.

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**Prescribing of ‘Coxibs’**

The ADTC would like to remind prescribers that ‘coxibs’, e.g. celecoxib (Celebrex®), etoricoxib (Arcoxia®) should not be prescribed as 1st line anti-inflammatory agents for any indication.

They are approved for use as 3rd line options in patients when at least 2 formulary choice standard NSAIDs (ibuprofen, naproxen, diclofenac) are ineffective, not tolerated or inappropriate.

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**Use of Unlicensed Metolazone in Heart Failure**

Metolazone (Metenix®) was discontinued in early 2012 by the manufacturer Sanofi and there is no alternative supply of licensed metolazone in the UK. Local heart failure specialists agreed that patients should be switched to bendroflumethiazide. However, anecdotal evidence has emerged within Fife that some patients are not as well managed on bendroflumethiazide.

The ADTC, having considered the options, has agreed that unlicensed metolazone may prescribed in a small group of patients whose symptoms are not adequately controlled with a maximum tolerated dose of bendroflumethiazide (up to 10mg) when recommended by a heart failure specialist.

Community pharmacies can obtain supplies of unlicensed metolazone via importers such as Phoenix or IDIS.

**Key Message**

Unlicensed metolazone should only be prescribed on the recommendation of heart failure specialist when patients remain symptomatic despite being prescribed a maximum tolerated dose of bendroflumethiazide.

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**Denosumab 60mg (Prolia®)**

In December 2010, the Scottish Medicines Consortium (SMC) recommended the use of denosumab as a 2nd line option for the treatment of postmenopausal osteoporosis in women where oral bisphosphonates (alendronate and risedronate) have been ineffective, not tolerated or contraindicated.

As this was a novel agent at the time, NHS Fife limited its use to specialist use only.

After a further review the ADTC have approved a change to the formulary status of denosumab. Once it has been initiated in secondary care then further injections can be prescribed in primary care. It should be noted that denosumab (Prolia®) is a subcutaneous injection that should be administered once every 6 months only.

Prescribers are reminded of the recent safety advice from the MHRA1 that stated all patients prescribed denosumab 60mg for osteoporosis should maintain an adequate intake of calcium and vitamin D or be prescribed appropriate supplementation with calcium and vitamin D (Fife Formulary choice Adcal D3®).

**Reference**

Updated Formulary Sections

The following sub-sections of Chapter 4 of the Fife Formulary have been updated and approved for use.

Hypnotics & Anxiolytics
Key points to note in this section include –
- Zopiclone is now the 1st line choice hypnotic.
- Zolpidem is now non-formulary.
- New sub-section on prescribing of melatonin.
- A new sub-section on anxiety disorders -
  - 1st line choices - Citalopram, fluoxetine and sertraline +/- psychological therapies
  - 2nd choices – Clomipramine and venlafaxine +/- psychological therapies

Psychoses
Key points to note in this section include –
- Oral drug choices for psychoses have been amended
  - 1st line choices are chlorpromazine, olanzapine and risperidone
  - 2nd line choices are amisulpride, aripiprazole (Abilify®), haloperidol and quetiapine
- Drugs now considered non-formulary are – promazine, sulpiride, trifluoperazine, zuclopenthixol (acetate and dihydrochloride salts)
- Preferred clozapine brand for use in NHS Fife is Zaponex®
- Paliperidone (Xeplion®) is now included as a 2nd generation depot injection as an alternative to risperidone (Risperdal Consta®)

Antidepressants
Key points to note in this section include –
- Formulary choice SSRIs remain as citalopram, fluoxetine and sertraline.
- Escitalopram remains non-formulary
- Trimipramine is now non-formulary
- MAOIs are restricted to specialist initiation

CNS/ADHD
Key points to note in this section include –
- For the treatment of ADHD
  - 1st line choice is methylphenidate
  - 2nd line choice is atomoxetine
  - 3rd line choice is dexmefetamine
- New sub-section on the prescribing of melatonin
- Modafanil is restricted to specialist initiation only and is only recommended for use in narcolepsy.

Obesity
Key points to note in this section include –
- Diet and lifestyle should be considered as the 1st line option.
- Orlistat should only be considered after a 3 month weight management programme.
- Orlistat should only be continued beyond 3 months if there is a >5% loss in body weight. Treatment should be reviewed again after 12 months to assess ongoing use.

Parkinsonism and Related Disorders
Key points to note in this section include –
- Benzatropine and trihexiphenidyl are now non-formulary
- Antimuscarinics should not be prescribed for idiopathic Parkinson’s disease.

Addictions
Key points to note in this section include –
- There are new sub-sections highlighting formulary options for alcohol detoxification, vitamin supplementation, alcohol relapse prevention, opioid detoxification, opioid maintenance prescribing, opioid relapse prevention and benzodiazepine maintenance prescribing.
- Links are included throughout to NHS Fife Addiction Service Guidelines.

Nicotine Dependence
Key points to note in this section include –
- Specialist support is recommended for all patients along with drug therapy.
- 1st line choice NRT formulation is patches. 2nd line choices are gum, the inhalator, lozenges and the oral spray.
- Varenicline should be considered 2nd line, after patients have failed on NRT.
- NRT and varenicline should normally be only prescribed for a maximum of 12 weeks.
- Bupropion is now non-formulary.

Dementia
Key points to note in this section include –
- Donepezil and galantamine are 1st line choices in mild to moderate disease.
- Rivastigmine is a 2nd line choice in mild to moderate disease.
- Memantine is now included as a formulary choice for moderate to severe Alzheimer’s disease.

Copies of the updated Chapter 4 of the Fife Formulary have been distributed electronically. Further copies of the updated sections can be accessed / downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Fife Formulary or via the Fife Formulary link on the NHS Fife intranet homepage.

Ensuring compliance with formulary choices is one of the ways that NHS Fife can ensure that the most cost-effective products are used for our patients.
Guidance

Palliative care
In line with most other Health Boards, NHS Fife is no longer producing its own set of guidelines for palliative care. Instead work is in progress to develop national guidance over the next 18 months or so. In the meantime NHS Fife ADTC have agreed to adopting the guidelines produced by NHS Lothian.

The NHS Fife Palliative Care Guidelines on the ADTC website has been updated with links to the relevant NHS Lothian documents. Where there is a difference in Formulary choices between NHS Fife and NHS Lothian these are highlighted in the NHS Fife Guidelines. The NHS Fife Palliative Care Guidelines and links to the NHS Lothian documents can be accessed from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Guidance documents/ Formulary appendices and then the link for Fife Wide Palliative Care.

Schizophrenia
NHS Fife Formulary Appendix 4A – ‘Guidance on Drug Treatment of Schizophrenia in Patients 18 years and over’ has been reviewed and updated.

Key Information in Appendix 4A includes:
• Good practice recommendations on the management of patients with schizophrenia.
• Management of patients with a 1st episode of schizophrenia, management of patients with a relapse or acute exacerbation.
• Table summarising the relative side-effect profile of different antipsychotic medication.

Antidepressants
NHS Fife Formulary Appendix 4B – ‘Guidance for the use of Pharmacological Agents for the Treatment of Depression in Adults (18 years and over)’ has been reviewed and updated.

Key Information in Appendix 4B includes:
• Information on assessing and diagnosing patients.
• Suitable antidepressants for patients with co-morbidities e.g. cardiovascular disease, at risk of suicide, risk of seizures, patients who are pregnant or breastfeeding, patients at risk of anticholinergic side-effects, patients with sexual dysfunction and patients requiring sedation.
• Key features of Fife Formulary antidepressants including new safety information for citalopram.
• Advice on switching and stopping antidepressants.
• Key patient counselling points.

Smoking Cessation
NHS Fife Formulary Appendix 4D – ‘Stop Smoking Guidance’ has been reviewed and updated.

The guidance document has been updated to reflect changes to the Fife Formulary choices on nicotine dependence.

Key Information in Appendix 4D includes:
• Advice on how to assess patient’s willingness to quit.
• Different pharmacological options available (1st line NRT, 2nd line varenicline).
• The follow-up of patients during their quit attempt.
• Advice on different formulations of NRT that are listed in the Fife Formulary.

Copies of the above appendices have been distributed electronically within NHS Fife. Further copies of the above can be accessed / downloaded from the ADTC website www.fifeadtc.scot.nhs.uk/ by clicking on the link for Fife Formulary or via the Fife Formulary link on the NHS Fife intranet homepage.

SMC Recommendations

Medicines accepted for use by SMC

Formulary Choices – Products that are recommended within Fife and should be used in the majority of patients.

Restricted Use – Products that have been approved by the SMC for a limited indication or for a niche group of patients. Appropriate for them to be prescribed for patient groups that have been approved by the SMC / Fife ADTC.

Not Preferred – Products that have been approved by the SMC but agreed in Fife that suitable Formulary choices are already available. These products should only be used when Formulary products have been ineffective, not tolerated or are contra-indicated.

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication assessed</th>
<th>Fife ADTC decisions &amp; comments</th>
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<tbody>
<tr>
<td>Colecalciferol 800 international units (equivalent to 20 micrograms vitamin D3) capsules (Fultium-D3®) Internis Pharmaceuticals Ltd.</td>
<td>In adults, the elderly and adolescents for the prevention and treatment of vitamin D deficiency and as an adjunct to specific therapy for osteoporosis in patients with vitamin D deficiency or at risk of vitamin D insufficiency.</td>
<td>Included in the Fife Formulary. Vitamin D Deficiency 1st line choice for all causes of vitamin D deficiency. Primary Hyperparathyroidism 1st line choice for vitamin D insufficiency in symptomatic patients with primary hyperparathyroidism. Osteoporosis Restricted use when calcium + vit. D products are considered unsuitable, ineffective due to non-compliance or are not tolerated. Fife Formulary choice for calcium + vit. D products is Adcal D3®.</td>
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<tr>
<td>Product</td>
<td>Indication assessed</td>
<td>Fife ADTC decisions &amp; comments</td>
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| **Fingolimod (as hydrochloride), 0.5mg hard capsules (Gilenya®)**      | As single disease modifying therapy in highly active relapsing remitting multiple sclerosis (RRMS) for the following adult patient groups:  
  - Patients with high disease activity despite treatment with a beta-interferon.  
  - Patients with rapidly evolving severe RRMS or a significant increase in T2 lesion load as compared to a previous recent MRI.  
  **SMC restriction:** restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year. | Included in the Fife Formulary for restricted use only - restricted to use as single disease modifying therapy in highly active RRMS in adult patients with high disease activity despite treatment with a beta-interferon with an unchanged or increased relapse rate or ongoing severe relapses, as compared to the previous year.  
  Neurologist use only.  
  Advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland. |
| **Tocilizumab, 20mg/mL, concentrate for solution for infusion (RoActemra®)** | Tocilizumab monotherapy is indicated in patients who are intolerant to methotrexate or where continued treatment with methotrexate is inappropriate, for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists.  
  **SMC restriction:** tocilizumab is restricted for use in accordance with British Society for Rheumatology guidance on prescribing TNFα blockers in adults with rheumatoid arthritis (2005). | Included in the Fife Formulary as a 2nd/3rd line biologic option for this indication.  
  Specialist hospital use only.  
  Advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland. |
| **Tegafur/gimeracil/oteracil 15mg/4.35mg/11.8mg and 20mg/5.8mg/15.8mg hard capsules (Teysuno®)** | Treatment of advanced gastric cancer in adults when given in combination with cisplatin.  
  **SMC restriction:** tegafur/gimeracil/oteracil is restricted to use in patients with advanced gastric cancer who are unsuitable for an anthracycline, fluorouracil and platinum triplet first-line regimen. | Not included in the Fife Formulary.  
  Clinicians do not support formulary inclusion.  
  Preferred treatment would be capecitabine + cisplatin. |
| **Velaglucerase alfa 400 units powder for solution for infusion (VPRIV®)** | Long-term enzyme replacement therapy in patients with type 1 Gaucher disease. | Included in the Fife Formulary.  
  Specialist hospital use only.  
  Advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland. |
| **Ivabradine 5 and 7.5mg film-coated tablets (Procoralan®)**            | Chronic heart failure New York Heart Association (NYHA) II to IV class with systolic dysfunction, in patients in sinus rhythm and whose heart rate is ≥75 beats per minute (bpm), in combination with standard therapy including beta-blocker therapy or when beta-blocker therapy is contra-indicated or not tolerated.  
  **SMC restriction:** for initiation only in patients whose resting heart rate remains ≥75 beats per minute despite optimal standard therapy. | Included in the Fife Formulary for chronic heart failure when heart rate remains >75bpm and  
  1. Patient is taking optimal standard therapy  
  Or  
  2. Beta-blockers are contra-indicated or not tolerated. |
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<tr>
<th>Product</th>
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</table>
| Fluticasone propionate and formoterol fumarate metered dose inhaler, 50microgram/5microgram, 125microgram/5 microgram 250microgram/10 microgram (flutiform®) Napp Pharmaceuticals Ltd. | The regular treatment of asthma where the use of a combination product [an inhaled corticosteroid (ICS) and a long-acting \( \beta_2 \) agonist (LABA)] is appropriate:  
• for patients not adequately controlled on ICS and ‘as required’ inhaled short-acting \( \beta_2 \) agonist or  
• for patients already adequately controlled on both an ICS and a LABA. | Included in the Fife Formulary as a 2nd line treatment option at Step 3 for asthma in patients where the use of a combination MDI containing fluticasone and formoterol is considered suitable. |
| Nepafenac 1mg/mL eye drops, suspension (Nevanac®) Alcon Laboratories (UK) Ltd. | Reduction in the risk of postoperative macular oedema associated with cataract surgery in diabetic patients.                                            | Add to restricted list.  
Restricted to use as a prophylactic treatment in patients who develop post op macular oedema in the 1st eye and are then due to undergo cataract surgery in their second eye.  
Hospital use only. |
| Advilinium 322 micrograms inhalation powder (Eklira Genuair®) Almirall S.A. | Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).                        | Not included in the NHS Fife Formulary as local clinicians do not support the formulary inclusion.                |
| Perampanel, 2mg, 4mg, 6mg, 8mg, 10mg, 12mg film-coated tablets (Fycompa®) Eisai Ltd | Adjunctive treatment of partial-onset seizures with or without secondarily generalised seizures in patients with epilepsy aged 12 years and older.  
**SMC restriction:** use as a second-line adjunctive treatment in patients with refractory partial onset epilepsy. Treatment should be initiated only by physicians who have appropriate experience in the treatment of epilepsy. | Included in the NHS Fife Formulary as a 3rd line option in patients with refractory partial onset epilepsy.  
Specialist, hospital initiation only.  
Contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower. |
| Ranibizumab, 10mg/mL solution for injection (Lucentis®) Novartis Pharmaceuticals UK Ltd. | Treatment of visual impairment due to diabetic macular oedema (DMO) in adults.  
**SMC restriction:** treatment of visual impairment due to DMO in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline. | Included in the NHS Fife Formulary for the treatment of visual impairment due to diabetic macular oedema (DMO) in adults with best corrected visual acuity (BCVA) 75 Early Treatment Diabetic Retinopathy Study (ETDRS) letters or less at baseline.  
Specialist, hospital use only.  
Contingent upon the continuing availability of the patient access scheme or a list price that is equivalent or lower. |
| Sildenafil (as citrate) 20mg film-coated tablets and 10mg/mL powder for oral solution (Revatio®) Pfizer UK | Treatment of paediatric patients aged 1 year to 17 years old with pulmonary arterial hypertension. Efficacy in terms of improvement of exercise capacity or pulmonary haemodynamics has been shown in primary pulmonary hypertension and pulmonary hypertension associated with congenital heart disease  
**SMC restriction:** restricted to use on the advice of specialists in the Scottish Pulmonary Vascular Unit and from the Scottish Adult Congenital Cardiac Service. | Included in the NHS Fife Formulary - restricted list.  
Specialist initiation only by specialists working in the Scottish Pulmonary Vascular Unit or Scottish Adult Congenital Cardiac Service. |
<table>
<thead>
<tr>
<th>Product</th>
<th>Indication assessed</th>
<th>Fife ADTC decisions &amp; comments</th>
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<tbody>
<tr>
<td>Abiraterone (Zytiga®) 3.5mg powder for subcutaneous injection Janssen-Cilag Ltd.</td>
<td>With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. <strong>SMC restriction:</strong> abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen.</td>
<td>To be used in patients who have received only one prior standard docetaxel containing chemotherapy regimen. Advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland. Approved</td>
</tr>
<tr>
<td>Lanthanum carbonate 750mg and 1000mg oral powder (Fosrenol®) Shire Pharmaceuticals Contracts Ltd.</td>
<td>A phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). <strong>SMC restriction:</strong> as a second-line agent in the control of hyperphosphataemia in chronic renal failure patients on haemodialysis or CAPD where a non-aluminium, non-calcium phosphate binder is required.</td>
<td>Included in the NHS Fife formulary. To be used as a 2nd line option in patients who require a non-aluminium, non-calcium binding agent. Hospital use only.</td>
</tr>
<tr>
<td>5-aminolaevulinic acid (as hydrochloride), 78mg/g, gel (Ameluz®) Biofrontera Bioscience GmbH</td>
<td>Treatment of actinic keratosis of mild to moderate intensity on the face and scalp (Olsen grade 1 to 2).</td>
<td>Not included in NHS Fife formulary as local clinicians do not support formulary inclusion. Photodynamic therapy is not provided in NHS Fife.</td>
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<tr>
<td>Olmesartan medoxomil / amlodipine besilate / hydrochlorothiazide (Sevikar HCT®) Daiichi Sankyo UK Ltd.</td>
<td>In adult patients whose blood pressure is not adequately controlled on the combination of olmesartan medoxomil and amlodipine taken as dual-component formulation.</td>
<td>Not included in the NHS Fife formulary as local clinicians do not support formulary inclusion. Fife Formulary choices for angiotensin receptor blockers are losartan, candesartan and irbesartan.</td>
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### Summary of Approved Lothian Formulary Committee Decisions for SCAN Medicines August - December 2012

<table>
<thead>
<tr>
<th>Product</th>
<th>Indication assessed</th>
<th>Place in Therapy</th>
<th>Lothian Formulary Committee Decision</th>
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<tbody>
<tr>
<td>Abiraterone (Zytiga®)</td>
<td>With prednisone or prednisolone for the treatment of metastatic castration resistant prostate cancer (mCRPC) in adult men whose disease has progressed on or after a docetaxel-based chemotherapy regimen. <strong>SMC restriction:</strong> abiraterone is accepted for use in patients who have received only one prior chemotherapy regimen.</td>
<td>To be used in patients who have received only one prior standard docetaxel containing chemotherapy regimen. Advice is contingent upon the continuing availability of the patient access scheme in NHS Scotland.</td>
<td>Approved</td>
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</table>
Medicines not recommended by SMC

Vemurafenib (Zelboraf®) is not recommended as monotherapy for the treatment of adult patients with BRAF V600 mutation-positive unresectable or metastatic melanoma. Lack of clinical benefits compared to cost, lack of robust economic analysis.

Bevacizumab (Avastin®) is not recommended in combination with carboplatin and paclitaxel for the front-line treatment of advanced (International Federation of Gynaecology and Obstetrics [FIGO] stages III B, III C and IV) epithelial ovarian, fallopian tube, or primary peritoneal cancer. Lack of evidence of economic benefits.

Tocofersolan oral solution (Vedrop®) is not recommended for vitamin E deficiency due to digestive malabsorption in paediatric patients suffering from congenital chronic cholestasis or hereditary chronic cholestasis, from birth (in term newborns) to 16 or 18 years of age, depending on the region. Lack of evidence of economic benefits.

Caffeine citrate (Peyona®) is not recommended for treatment of primary apnoea of premature newborns. Non submission by the manufacturer.

Pasireotide (Signifor®) is not recommended for treatment of adult patients with Cushing’s disease for whom surgery has failed. Non submission by the manufacturer.

Strontium ranelate (Proteos®) is not recommended for treatment of osteoporosis in men at increased risk of fracture. Non submission by the manufacturer.

Zonisamide (Zonegran®) is not recommended as monotherapy for the treatment of partial seizures (with or without secondary generalization) in adults with newly diagnosed epilepsy. Non submission by the manufacturer.

Argatroban (Exembol®) is not recommended for anticoagulation in adult patients with heparin-induced thrombocytopenia type II who require parenteral antithrombotic therapy. Lack of evidence of clinical and economic benefits.

Adalimumab (Humira®) is not recommended for the treatment of moderately to severely active Crohn’s disease, in adult patients who have not responded despite a full and adequate course of therapy with a corticosteroid and/or an immunosuppressant, or who are intolerant to or have medical contraindications for such therapies. Non submission by the manufacturer. However in line with NICE MTA 187, adalimumab is a treatment option for patients with severe active Crohn’s disease in patients whose disease has not responded to conventional therapy. Specialist, hospital use only.

Interferon beta-1a (Rebif®) is not recommended for use in patients with a single demyelinating event with an active inflammatory process, if alternative diagnoses have been excluded, and if they are determined to be at high risk of developing clinically definite multiple sclerosis. Non submission by the manufacturer.

Pazopanib (Votrient®) is not recommended for the treatment of adult patients with selective subtypes of advanced soft tissue sarcoma (STS) who have received prior chemotherapy for metastatic disease or who have progressed within 12 months after (neo) adjuvant therapy. Efficacy and safety has only been established in certain STS histological tumour subtypes. Lack of evidence of economic benefits.

Racecadotril (Hidrasec Infants®, Hidrasec Children® sachets) is not recommended for complementary symptomatic treatment of acute diarrhoea in infants older than three months and in children, together with oral rehydration and the usual support measures, when these measures alone are insufficient to control the clinical condition. Lack of evidence of clinical and economic benefits.

Racecadotril (Hidrasec® capsules) is not recommended for symptomatic treatment of acute diarrhoea in adults when causal treatment is not possible. Non submission by the manufacturer.

Dates for 2012 ADTC Meetings

<table>
<thead>
<tr>
<th>ADTC meeting</th>
<th>Deadline for submission of papers and agenda items</th>
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<tr>
<td>20 February</td>
<td>4 February</td>
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<td>24 April</td>
<td>8 April</td>
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<td>19 June</td>
<td>3 June</td>
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<td>28 August</td>
<td>12 August</td>
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<td>16 October</td>
<td>30 September</td>
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<td>4 December</td>
<td>18 November</td>
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Contact the Clinical Effectiveness Pharmacist on 01592 226915 for advice on making a formulary submission or for clarification on the process for approval of guidance documents.

The information provided in this bulletin is correct at the time of publishing but is subject to change as new clinical information becomes available.

If you require this newsletter in alternative formats please telephone 01592 226915

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